

**A STUDY ON PREVALENCE OF DIABETIC FOOT ULCER AND QUALITY
OF LIFE OF TYPE 2 DIABETES MELLITUS PATIENTS IN A
MULTISPECIALITY HOSPITAL**

A Dissertation submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

Chennai-600032



In partial fulfillment of the requirements for the award of degree of

MASTER OF PHARMACY

IN

PHARMACY PRACTICE

Submitted by

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Under the Guidance of

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EVALUATION CERTIFICATE

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ABSTRACT

A Study on Prevalence of Diabetic Foot Ulcer and Quality of Life of Type 2 Diabetes Mellitus Patients in a Multi-Specialty Hospital

Aim: The present study aim is to assess the prevalence of diabetic foot ulcer and the quality of life among type 2 diabetes mellitus.

Methods: A prospective observational study was conducted in 146 consecutive patients with type 2 diabetes mellitus in a multispeciality hospital. The demographic details were collected using data collection form and ferrans and powers QLI index questionnaire was used to assess the Quality of Life. The collected data from the subjects were analyzed by using ANOVA.

Results: The results showed that the prevalence of diabetic foot ulcer was 20.47% and the mean age of patient with diabetic foot ulcer was 55.5 ± 3.03 years. As per the study, Quality of Life of subjects were improved statistically with patient counseling in health and functioning domain ($p < 0.05$). The patients with more than 15 years of diabetes mellitus had no significant improvement in their quality of life.

Conclusion: The study concluded that 20.47% diabetic patients have foot ulcer. With regular patient counseling, maintenance of diet and exercise with good patient compliance improves the QOL of patients in day-to-day activities.

Key words: Diabetic foot ulcer, Quality of life, Type 2 diabetes mellitus.

ABBREVIATIONS

ANOVA	Analysis Of Variance
AWDC	Annual World Diabetes Congress
BMI	Body Mass Index
CDCP	Centers for Disease Control and Prevention
DM	Diabetes Mellitus
DPP4i	Di Peptidyl Peptidase 4 Inhibitors
GLP	Glucagon like Peptide
IDF	International Diabetes Federation
NPH	Neutral Protamine Hagedon
PHMB	Polyhexamethylene Biguanide
QOL	Quality Of Life
SGLT	Sodium Glucose co transporter 2 inhibitors
T2DM	Type 2 Diabetes Mellitus
UTS	University of Texas System
WHO	World Health Organization

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1. INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by increased glucose levels in the blood which contributes in the development of microvascular, macrovascular and neuropathic complications. Diabetes is emerging as a major health problems which increases the rate of morbidity and mortality.⁽¹⁾ According to WHO estimation, the global prevalence of diabetes is increasing at a rate of more than 120%. In 1995 there were 135 million people affected with diabetes mellitus, in 2000 the number rose to 171 million. **World wide** the projected estimate of the people likely to get affected with diabetes by 2025 will be 300 million and by 2030 will be 366 million. **In India** it was 31.7 million in 2000 and will be increased as 79.4 million in 2030.⁽²⁾ The diabetes epidemic and diabetes rates in South Asia vary from 3.3% in Nepal to 10% in India.⁽³⁾

World health organization estimates 60% of diabetic population will be from developing countries of Asia by 2025. The highest regional prevalence is reported as 10.2% in North America followed by 6.7% in south Asia. The most important demographic change is the increase in the proportion of people >65 years of age prone to diabetes across the world. According to the 20th Annual World Diabetes Congress(AWDC), 50.8 million of individuals have diabetes in India. India is one of the top ten country for numbers of people aged 20-79 years with diabetes in 2010 and 2030. The prevalence of diabetes is increased due to change in lifestyle modification such as decreased physical activity and increased obesity.

International diabetic federation estimates that diabetes represents the fourth leading cause of global deaths.⁽²⁾

According to the Lancet study, China, India and USA are the top three countries with a large number of diabetic population. In 1980, 20.4 million in China was increased to 102.9 million in 2014, the rise has been equally dramatic in India from 11.9 million in 1980 to 64.5 million in India. Prevalence of diabetes has more than doubled for men in China and India (3.5 percent to 9.9 per cent in China and 3.7 per cent to 9.1 per cent in India). It has also

increased by 50 per cent among women in China (5.0 per cent to 7.6 per cent) and 80 per cent among women in India (4.6 percent to 8.3 percent). The prevalence of type 2 diabetes is projected to rise from 246 million people to 380 million people by 2025 worldwide. It is representing as 7.1% of global adult population.⁽⁴⁾

Diabetes have both long term and short term complications include macrovascular (ischemic heart disease, stroke, peripheral vascular disease) and microvascular (diabetic neuropathy, diabetic nephropathy, diabetic retinopathy). These in turn have a negative impact on health related quality of life⁽⁵⁾

The prevalence of diabetes is increasing worldwide resulting in foot complications, which leads to poor quality of life and increased cost of living. More than 60% of diabetic patients are affected by neuropathy. Overall, the life expectancy is about 7 to 10 years shorter than for people without diabetes because of increased mortality from diabetic complication.

Among diabetes mellitus complications, foot ulceration is the most commonly affected and approximately 15% of diabetic patients suffer during their life time. All people with diabetes have a chance to develop foot pain and foot ulcer, but it can be easily prevented by good foot care maintenance.

According to the file documented on 1999, 20th century, there was inadequate evidence on trials or data related to prevalence, morbidity and health care costs of diabetic foot disease. But on 21st century, there are lot of information regarding diabetic foot ulcer particularly in these decades. Foot ulcer plays an important role in the lower extremity amputation that too in adults with diabetes mellitus. By 2030 it is estimated that more than 550 million people around the world will have diabetes. Approximately 25% of these patients will develop foot ulcers during their lifetime, which requires advanced diabetic wound treatment to prevent complications.

Type 2 diabetes affect the patients general health and well-being in various ways. For example, severe diet restriction and daily intake of oral medication or insulin may adversely affect an individuals health related quality of life. In addition, the long-term complications of diabetes, such as nephropathy, neuropathy, heart disease, and stroke, with their considerable impact on health, may also have a negative effect on quality of life.⁽⁵⁾ Some patients may have low energy levels, insomnia(sleep disturbances), physical dysfunction and many other problems.⁽⁶⁾

WHO defines health as being not only the absence of disease and infirmity but also presence of physical, mental and social well being.⁽²⁾ Assessment of quality of life is considered as important measure of outcome in chronic disease management.⁽⁷⁾

QOL as the persons perception and understanding of his living conditions in terms of culture and values of the society in line with goals, expectations, standards and interests of individuals.⁽⁸⁾ QOL is defined by Ferrans as “a person’s sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her.”⁽⁹⁾

It is very important to measure the quality of life in type 2 diabetes mellitus patients having foot ulcer. Because to know how much they are satisfied and/or dissatisfied with their life in health and functioning domain, social and economical domain, psychological domain and family domain.

1.1 DIABETES MELLITUS

1.1.1 DEFINITION

Diabetes mellitus [DM] is a group of metabolic disorder characterized by hyperglycemia and associated with abnormalities in carbohydrate, fat and protein metabolism.

1.1.2 Etiology

Type 1- genetic factors,

Type 2-Many people with type 2 diabetes have a family member affected with either type 2 diabetes or other medical problems associated with diabetes, such as high cholesterol levels, high blood pressure, or obesity.

The lifetime risk of developing type 2 diabetes is 5 to 10 times higher in first-degree relatives like sister, brother, daughter, son of a person with diabetes compared with a person with no family history of diabetes.

Environmental conditions — Environmental factors such as what we intake and how activeness are combined with genetic causes, affect the risk of developing type 2 diabetes.

1.1.3 Epidemiology

The International diabetes federation (IDF) estimates that 246 million adults worldwide have diabetes mellitus. The world prevalence of diabetes among adults (aged 20-75 years) was 6.4% in 2010, 285 million adults were affected and it will increase in 2030 as 7.7%, 439 million adults. Between 2010 and 2030, there will be a 69% increase in adults number with diabetes in developing countries and 20% increase in developed countries.⁽¹⁰⁾ It is known that approximately 90% of diabetic patients have type 2 diabetes mellitus.⁽¹¹⁾

1.1.4 DIAGNOSIS

According to the World Health Organization, the diagnosis of diabetes mellitus had a criteria such as

Fasting blood glucose test The blood sugar level should be 7.0 mmol/L (126mg/dl). The report states that the diagnosis should be confirmed after two or three repetitions of symptoms or blood glucose determination.

Random blood sugar test The blood sample will be collected at a random time after last ate. The blood glucose level should be less than 200mg/dl or 11.1 mmol/L.

Heamoglobin A1C test The blood sample will be collected and tested at any time of the day(before eating or after eating) measures the average blood sugar level over the past two to three months. Normal values for A1C are 4 to 5.6 percent. The A1C test can be done at any time of day (before or after eating).

Oral glucose tolerance test the blood sample will be collected after the fast for atleast eight hours or overnight and then drink a sugary solution and the blood glucose level will be measured after two hours. The blood sugar level less than 140mg/dl(7.8 mmol/L) is normal, 140 to 199 mg/dl(7.8 to 11 mmol//L) is considered as prediabetes. This is sometimes referred to as impaired glucose tolerance. ⁽¹⁰⁾

1.1.5 CLASSSIFICATION

The WHO classification includes both clinical stages (normoglycemia, impaired glucose tolerance/impaired fasting glucose, diabetes)

Type 1 - beta cell destruction with little or no endogenous insulin secretory capacity. It is otherwise known as juvenile-onset diabetes, results from a cellular – mediated autoimmune destruction of the beta-cells of the pancreas. It is also due to autoimmune disorder.

Type 2 - ranges from relative insulin deficiency to disorders of insulin secretion and insulin resistance. The pancreas create more amount of insulin sometimes but the body is not able to use it effectively.⁽¹⁾ This diabetes goes undiagnosed for many years because the hyperglycemia develops gradually and at earlier stages not severe to notice any of the symptoms of diabetes. It is also a genetic disorder definitely having a family history.

Other specific types –

Gestational diabetes

Genetic defects of beta cell function

Genetic defects in insulin secretion

Uncommon forms of immune mediated diabetes⁽¹⁰⁾

1.1.6 SIGNS AND SYMPTOMS

Polyuria

Polydipsia

Polyphagia

Fatigue

Blurred vision

Recurrent vaginal infection

Trouble in thinking and concentrating⁽¹⁰⁾

1.1.7 PHARMACOLOGICAL TREATMENT

Oral hypoglycemic agents

1. Biguanides - metformin
2. Thiazolidinediones – pioglitazone, rosiglitazone
3. Meglitinides – repa-g, nate-g
4. Sulfonylureas - glipizide, gliclazide, glyburide, glimepiride
5. Alpha glucosidase inhibitor – acarbose, voglibose, miglitol
6. DPP-4 inhibitors – vildagliptin, linagliptin, sitagliptin, saxagliptin, alogliptin
7. GLP receptor agonist – exenatide, liraglutide
8. SGLT 2 inhibitors – dapagliflozin, canagliflozin, ipragliflozin
9. Dopamine D2 receptor agonist – bromocriptine
10. Amylin analog – pramlintide
11. Bile acid binding resin – colestevam⁽²⁴⁾

Insulin therapy

Short acting insulin - regular insulin and insulin analogues (aspartate, lispro, glulisine)

Intermediate acting insulin - neutral protamine hagedon(NPH) insulin and lente insulin

Long acting insulin - ultralente insulin and protamine zinc insulin

1.1.8 NON PHARMACOLOGICAL TREATMENT

- Diet and Exercise
- Smoking Cessation
- Yoga
- Physical activity

1.2 DIABETIC FOOT ULCER

A diabetic foot ulcer is an open sore, no matter how large or deep that can develop anywhere on the foot or toes that lost the protective layer of the skin. Non traumatic lesions of the skin (partial or full thickness) on the foot of a person who has diabetes mellitus⁽¹²⁾

1.2.1 ETIOLOGY:

The etiology of foot ulcer has many components. One of the past multicenter study reported that 63% of diabetic foot ulcer due to peripheral sensory neuropathy, trauma, and deformity. Some other factors includes ischemia, callus formation, and edema. Ulcers are the primary cause leads to amputation and many risk factor for foot ulcers are the predisposing factor for amputation.⁽⁴⁶⁾ Long term hyperglycemia impairs the immune system or immune response which in turn leads to poor healing of cuts and wounds. The most frequent underlying etiologies are neuropathy, trauma, deformity, high plantar pressures, and peripheral arterial disease. Neuropathy is often a predisposing factor to ulceration and amputation. Diabetic ulcers are most commonly caused by

1. Poor circulation- a form of vascular disease in which blood doesn't flow to the feet efficiently.
2. High blood sugar (hyperglycemia)- slow down the healing process
3. Nerve damage – loss of sensation, feels tingling and painful initially which results in painless wounds that can cause ulcers.
4. Irritated or wounded feet - dry skin is common and corns, calluses, cracking and bleeding wounds may occur.

1.2.2 EPIDEMIOLOGY

Diabetic foot ulcer is one of the most common complication in diabetes patients which leads to hospitalization and in severe cases amputations required. Diabetic foot patients may also have other complications of diabetes. The prevalence of foot ulcer was as high as 11.6% by Centre For Disease Control And Prevention (CDCP) (2003) in united states. In a

population based study, USA reported 10.6% of diabetic foot ulcers.⁽¹⁴⁾ Prevalence rate of diabetes in Indians is 2.4% in rural and 12-17% in urban population. Foot ulcers will occur in 5-10% of the diabetic population. Ulceration is the most common cause of amputation.⁽⁴⁾ The various lower limb complications in diabetic patients are peripheral neuropathy, charcot arthropathy, foot ulcers, infections, and lower extremity amputations which may lead to hospitalization and disability among the diabetics.⁽⁴⁾

In India, prevalence of diabetic foot ulcer patients in a clinic population is 3% which is comparatively lower than western countries. The prevalence of foot complications such as peripheral vascular disease 5%, neuropathy 15% and infections 7.6%. In India, 55% of foot ulcers are neuropathy, 35% were neuro ischemic and 10% were ischemic(blood vessel involvement).⁽¹⁵⁾

1.2.3 CLASSIFICATION OF DIABETIC FOOT LESIONS

There are 3 main classification system which is commonly used in the clinical diagnosis of foot ulcer.

1. Wagner Meggit classification
2. Depth- Ischemic classification
3. University of texas classification

Wagner meggit classification

The Wagner system assess ulcer depth and presence of osteomyelitis or gangrene by using the following grades:

Grade 0 – no open lesion

Grade 1 – superficial ulcer

Grade 2 – Probing to tendon or capsule

Grade 3 – Deep ulcer with osteomyelitis, abscess, or joint sepsis

Grade 4 – local gangrene – fore foot or heels

Grade 5 – gangrene of entire foot

Depth ischemic classification:

This is a modified system of wagner-meggitt classification. The modified classification is used to distinguish between wound and vascularity of foot easily and more accurately to elucidate grade 2 and 3.⁽¹⁴⁾

The university of texas system

This system assess the ulcer depth, the presence of wound infection, and the presence of clinical signs of lower-extremity ischemia. The grades of the UT system are as follows:

Grading - description

Grade 0 – pre or post ulcerative site that has healed

Grade 1 – superficial wound not involving tendon, capsule, or bone

Grade 2 – wound penetrating to tendon or capsule

Grade 3 – wound penetrating to bone or joint

Stages - description

Stage A - no infection or ischemia

Stage B – infection present

Stage C – ischemia present

Stage D – infection and ischemia present.⁽¹⁶⁾

1.2.4 PATHOPHYSIOLOGY

More than 60% of foot ulcer is caused by neuropathy. It is a metabolic abnormalities induced by hyperglycemia. One of the common mechanism of action is polyol pathway. Hyperglycemic state increases the action of an enzyme aldose reductase and sorbitol dehydrogenase results in the conversion of intracellular glucose to sorbitol and fructose.

Causative factors:

- The casual pathways leading to the foot ulceration include several component causes, the most important one is peripheral neuropathy which leads to loss of sensation.
- The second factor includes the higher plantar pressure which leads to joint deformity and joint immobility.
- The third component cause is trauma, especially when repetitive.

Contributory factors

- Diabetes
- Arthrosclerotic peripheral vascular disease

1.2.5 SIGNS AND SYMPTOMS

Foot ulcers are a common complication of poorly controlled diabetes, forming as a result of skin tissue breaking down and exposing the layers underneath, commonly found on big toes, balls of feet and to the bones from the feet.

One of the first signs of a foot ulcer is drainage from foot that might stain stocks or leak out in shoes, unusual swelling, irritation, redness, odors from one or both feet.

Symptoms as follows;

- Cellulitis,
- Deep skin and soft tissue infections,
- Acute osteomyelitis,
- Chronic osteomyelitis.

1.2.6 RISK FACTORS

The major two risk factors are peripheral neuropathy and poor glycemic control followed by other factors such as

1. Poorly fitted shoes
2. Not washing the feet regularly or thoroughly
3. Improper trimming of nails
4. Alcohol consumption
5. Tobacco use(decreases the blood circulation)
6. Obesity⁽¹⁸⁾

1.2.7 TREATMENT

For obese people, extra pressure causes the foot pain. The choice of antibiotics should be based upon the severity and type of the infection and microorganisms.

Mild infections- oral antibiotics such as cephalexin, dicloxacillin, amoxicillin-clavulanate, or clindamycin are effective choices. If methicillin resistant staphylococcus aureus infection is suspected then clindamycin, trimethoprim-sulfamethoxazole, minocycline, or linezolid may be used. Gram negative aerobes and/or anaerobes- dual drug treatment- trimethoprim-sulfamethoxazole + amoxicillin-clavulanate or clindamycin + fluoroquinolone such as levofloxacin or moxifloxacin.

Moderate to severe infections - hospitalized for parenteral antibiotic therapy- nafcillin or oxacillin.

Moderate to severe infection with ischemia - ampicillin / sulbactam

Life or limb threatening infection – ticarcillin / clavulanate or piperacillin / tazobactam, with or without an aminoglycoside.

Surgical debridement - it is important in diabetic patients with chronic osteomyelitis. Debridement removes the infected, bony fragments which cannot be cured by antibiotics but can treat with antimicrobial therapy. In some cases, amputation is required.

Patients must try to control their glycemic levels in order to achieve an effective outcome through microbial eradication and tissue healing.⁽¹²⁾

OTC TREATMENTS

Dressings containing silver or silver sulphadiazine cream

Polyhexamethylenbiguanide (PHMB) gel or solutions

Iodine (either povidone or cadexomer)

Medical grade honey in ointment or gel form

Six key factors in treating a diabetic wound.

1. Initially wound assessment should be done on diabetic wounds - neuropathic, ischemic, and neuroischemic.
2. Tissue debridement - removal of necrotic tissue from a wound will reduce pressure and stimulates wound healing.
3. Infection control – due to high morbidity and mortality rates associated with diabetic wounds more aggressive forms of infection control are necessary. Oral and topical antibiotics are prescribed.
4. Moisture balance – choice of dressing is important. Alginates, hydrocolloids, and films ischosed.

5. Pressure offloading – pressure reduction or pressure offloading is done. Total contact casting is a non-removable thing which distributes the pressure evenly throughout the leg to reduce healing times. TCC is not always best especially for infected wounds. Removable offloading devices used such as removable cast walkers, scotchcast boots, or healing sandals.
6. Underlying factors - blood glucose levels, proper nutrition, high blood pressure, and smoking cessation.

1.2.8 PREVENTIVE MEASURES

1. Wash the feet everyday
2. Keep the feet dry and moisturized
3. Change the socks frequently
4. Wear proper fitting shoes
5. Trim the toe nails
6. Off loading⁽¹⁸⁾

2. LITERATURE REVIEW

Yusuf S et al., (2016) studied the prevalence and risk factor of diabetic foot ulcers in a regional hospital as an observational epidemiological study and it was concluded as to educate the patients with high risk foot to prevent them from diabetic foot ulcer and risk factors.⁽⁹⁾

Sriram S et al., (2016) was conducted a prospective comparative study on impact of pharmaceutical care activities on diabetic patients at a private hospital and concluded that the patient counseling of disease, medications, modification of lifestyle improves the quality of life and glycemic control.⁽⁵⁵⁾

Timar R, et al., (2016) conducted the study on factors influencing the quality of life perception in patients with type 2 diabetes mellitus.' Cross sectional study was conducted in 198 type 2 diabetic patients by using the questionnaires and concluded that the diabetic complications decrease the perception of quality of life in co-morbid state such as retinopathy, neuropathy and cardiac autonomic neuropathy.⁽¹⁴⁾

Masoom Shahnavazi et al., (2016) studied the relationship between emotional intelligence and quality of life in hemodialysis patients'. A descriptive correlational study concluded that the emotional intelligence of the hemodialysis patients should be improved by training them so that quality of life in hemodialysis patients will be good.⁽⁸⁾

Anand A et al., (2016) studied clinico-microbiological study of diabetic foot ulcer patients to identify risk factors and their correlation with prognosis in tertiary care hospital in India' and concluded that male sex, smoking, neuropathy, 50 years of age and infection with Gram negative organisms were the most important risk factors for the development of diabetic foot.⁽⁶²⁾

Andres PR et al.,(2015) studied 'Quality of life in type 2 diabetes mellitus patients requiring insulin treatment and concluded as scores of QOL in selected T2DM patient population did not differ from the those reported in studies that included patients from high-income countries where there is access to a high level of diabetes care and also increase the healthcare

providers and awareness of the patients about their quality of life and helps to overcome the barriers that delay insulin treatment.⁽²⁸⁾

Asiye D Akyol et al., (2015) studied 'Reliability and validity of Turkish version of Quality of life index in stroke patients' concluded as the findings from this study support the validity, reliability and feasibility of the QOL among stroke patients.⁽²⁴⁾

Kahsu Gebrekirstos et al., (2015) conducted a study on prevalence and factors associated with diabetic foot ulcer the study was concluded with poor glycemic control, not taking care of foot properly and wearing inappropriate shoes were the main reasons to develop diabetic foot.⁽¹⁰⁾

Miguel C M et al., (2015) studied 'Health-related quality of life in patients with type 2 diabetes mellitus in a rural area.' concluded the study with poor self-perceived health-related quality of life(HRQOL) in type 2 diabetes mellitus patients.⁽¹⁾

Mugomri M et al., (2015) studied 'Determinants of quality of life among the elderly living with arthritis in manonyane community, Lesotho.' concluded the study with the pain and worries decrease the quality of life in the aspect of health and functioning and social and economic subscale.⁽¹⁶⁾

Yazdanpanah L et al., (2015) studied literature review on the management of diabetic foot ulcer. The study was concluded that for the management of diabetic foot ulcer, glycemic control, wound debridement, offloading and surgery can be done.⁽⁵⁸⁾

V Jyothylekshmy et al (2015) conducted the study on epidemiology of diabetic foot complications in a podiatry clinic. Retrospective study concluded with Staphylococcus aureus is the main causative pathogen along with Pseudomonas aeruginosa and fluroquinolones were the antibiotics used empirically in this study.⁽⁴⁶⁾

Bediluderibe et al., (2014) conducted a cross sectional study on 'Prevalence and factors influencing diabetic foot ulcer among diabetic patients attending arbaminch hospital and concluded that patients with diabetes developed foot ulcer. Rural residence, duration of diabetes, occupation, mean arterial pressure, presence of co-morbidity are factors associated with diabetic foot ulcer.⁽¹²⁾

Elhamghasemi et al., (2014) Studied 'Quality of life in women with coronary artery disease and concluded as there was a significant relationship between QOL and educational level, marital status, income and duration of disease ($p < 0.05$).⁽⁶⁾

Anumol Mathew et al., (2014) studied quality of life among type II diabetes mellitus patients in South India as a descriptive study with 100 patients and concluded with significance of incorporating techniques to improve the quality of life of type 2 diabetes mellitus patients by providing an information booklet to achieve a better quality of life.⁽⁶⁸⁾

Harish kumarsomappaet al., (2014) conducted a study with the objectives to assess Quality of life among type 2 diabetic patients and concludes that correlations revealed that there is positive correlation with QOL domains and all the diabetic patients need improvement with proper treatment regimen ensures good glycemic control.⁽³³⁾

Leelavathi D Acharya et al., (2014) studied 'Development and validation of quality of life assessment instrument for diabetic patients' and concluded the study with MDQoL-17 questionnaire was similar to the established RAND-36 and could be used as a tool to assess the quality of life in diabetic patients.⁽⁵⁴⁾

Abuawad S. S.Majed et al., (2013) conducted a study to assess the impact of DM on the health-related quality of life (HRQOL) of diabetic patients and concluded that DM disease has negative impact on HRQOL. Thus health care providers, particularly MOH health care providers must address its social consequences.⁽⁷¹⁾

P. Tamilselvi et al., (2013) conducted A descriptive study to assess the knowledge regarding diabetic foot ulcer among diabetic clients in a selected hospital and concluded that there is need to educate people regarding their disease to improve the health and quality of life of an individual.⁽³⁴⁾

Dr Amit Kumar C Jain et al., (2012) studied 'A new classification of diabetic foot complications: A simple and effective teaching tool' This was concluded with the newer classification can be used as a teaching tool helps in disseminating the knowledge about diabetic foot complications.⁽⁵⁷⁾

Kamal M Modh et al., (2011) studied an Impact of clinical pharmacist intervention on quality of life in type 2 diabetes mellitus' and concluded that patient education showed positive impact on improvement of knowledge, attitude, and practice which reflected an improvement of health related quality of life and also improves the medication adherence behavior.⁽²⁷⁾

Al-Maskari MY et al., (2011) studied 'Assessment of quality of life in patients with type 2 diabetes mellitus in Oman.' The result reveals that patients having diabetes for less than 5 years have overall better Quality of life. Patients with HbA1c less than 8% showed significant increase in their glycemic control satisfaction score.⁽³⁸⁾

K.P. Arun et al., (2010) studied the impact on pharmaceutical care on the clinical outcome of diabetes mellitus among rural population and concluded as the pharmaceutical care program was effective in improving the clinical outcome and HRQOL of diabetes patients in rural India.⁽²²⁾

Adepu Ramesh et al., (2009) conducted a study on community pharmacy based patient education on quality of life in type 2 diabetes mellitus and concluded that chronic diseases like diabetes affect the quality of life of patients and the education has a major role in improving the health care outcomes like glycemic control and quality of life. The quality of life score in all the four domains were observed and there was a significant decrease in the blood glucose level ($p < 0.05$).⁽²³⁾

Ghanassia E et al., (2008) studied 'long-term outcome and disability of diabetic patients hospitalized for diabetic foot ulcer'. A prospective study for 6.5 year follow up was conducted among 94 consecutive diabetic patients and the study concluded that the nephropathy was an important predictor of long-term outcome.⁽⁵⁹⁾

Vijay Viswanathan et al., (2006) studied 'Urban rural differences in the prevalence of foot complications in South Indian diabetic patients and concluded the reason for the high prevalence of foot infection could be attributed to greater prevalence of barefoot walking and prevalence of foot infection was higher among rural than urban patients amputations were also higher in rural than urban.'⁽⁵³⁾

Li Chen Lin Grae Yau et al., (2006) studied 'The efficacy of hyperbaric oxygen therapy in improving the quality of life in patients with wound problems. Finally the conclusion states that the patients quality of life has been improved when the wound is treated with HBOT.'⁽¹⁷⁾

Sarah Wild et al., (2004) conducted a study to estimate the prevalence of diabetes and the number of people of all ages with diabetes for years 2000 and 2030 concluded as their findings indicate that the diabetes epidemic will continue even if levels of obesity remain constant. Given the increasing prevalence of obesity, it is likely that these figures provide an underestimate of future diabetes prevalence.⁽¹⁴⁾

Probal K et al., (2003) studied to examine the long term outcome in terms of Amputation and mortality in new-onset diabetic foot ulcers stratified by etiology and concludes that foot ulcer not only affects the morbidity but also impairs the quality of life of patients and the mortality rate is reduced by decreasing the amputations in order to save both limb and life. The increased mortality appears to be independent of factors increasing ulcer risk.⁽⁵⁾

W. Ken Redekop et al., (2002) studied the health-related quality of life (HRQOL) and treatment satisfaction for patients with type 2 diabetes in the Netherlands and concluded the study with elderly patients, insulin therapy, obesity and the presence of complications are important determinants of HRQOL in patients with type 2 diabetes.⁽⁴⁵⁾

Samon O Oyiboet al., (2001) studied 'A comparison of two diabetic foot ulcer classification systems. The wagner and the university of texas wound classification systems.' Finally, for the group of study UT system was simple and easy to use and also better predictor of clinical outcome.⁽⁴⁾

Edward J. Boykoet al., (1999) prospectively studied the effects of diabetes characteristics, foot deformity, behavioral factors, and neurovascular function on foot ulcer risk among 749 diabetic patients and concluded that certain foot deformities, reduced skin oxygenation and foot perfusion, poor vision, greater body mass, and both sensory and autonomic neuropathy independently influence foot ulcer risk, thereby providing support for a multi factorial etiology for diabetic foot ulceration.⁽³⁷⁾

Matthew J. Young et al., (1994) studied 'The prediction of diabetic neuropathic foot ulceration using vibration perception thresholds.' study was concluded that VPT is an effective predictor of the risk of foot ulceration in diabetes and therefore could be used to target foot-care education to those patients most likely to benefit and, thereby, possibly improve its effectiveness.⁽³⁵⁾

3. AIM AND OBJECTIVES

3.1 AIM

The aim of the study was to determine prevalence of diabetic foot ulcer and quality of life of type 2 diabetes mellitus patients.

3.2 OBJECTIVES

- To assess the prevalence of foot ulcer patients.
- To determine the quality of life in T2DM patients using ferrans and powers quality of life index questionnaire.
- To determine the factors associated with QOL in diabetic patients.

4. PLAN OF STUDY

The study was carried out for a period of 1 year from June 2016 to April 2017. The proposed study has been designed as below.

PHASES	STEPS	ACTIVITY	PERIOD OF TIME
PHASE I	STEP 1	Identification of target area for possible research	2 months
	STEP 2	Literature survey	
	STEP 3	Define criteria and standards	
	STEP 4	Designing of Data entry form	
	STEP 5	Selecting the Questionnaire form	
PHASE II	STEP 6	Prospective collection of Data	6 month
PHASE III	STEP 7	Analysis of Data	1 month
PHASE IV	STEP 8	Presentation of Study Results	1 month

5. METHODOLOGY

5.1 STUDY TYPE

This was a Prospective Observational study

5.2 STUDY SITE

The study was conducted in 300 bedded multispecialty hospital located in Elayampalayam.

5.3 STUDY PERIOD

The study was approved (Ref No: SVCP/IEC/JUL/2016/07) by Institutional Ethical Committee of Vivekanandha Medical Care Hospital (Annexure-I). The study was carried out for the period of 1 year in the department of General Medicine.

5.4 POPULATION SIZE

Total 262 patients were screened and based on inclusion and exclusion criteria, 146 patients were recruited in our study after getting the patient consent (Annexure-II & III) and the data was collected in specially designed data entry form (Annexure-IV).

5.5 SELECTION CRITERIA

Inclusion Criteria

Patients with type 2 diabetes mellitus

Both the gender

Age \geq 30 years

Duration of diabetes \geq 5 years

Both Inpatients and Outpatients

Exclusion criteria

Pregnancy and lactation

Age < 30 years

Duration of diabetes < 5 years

Critically ill patients

5.6 SOURCES OF DATA

Patient's case report

Quality of life index questionnaire

5.7 STATISTICS

Data were analyzed by single factor ANOVA to detect significant differences between before and after patient counseling. Values are shown as the means \pm SD and differences were considered statistically significant at $p < 0.05$.

6. RESULTS

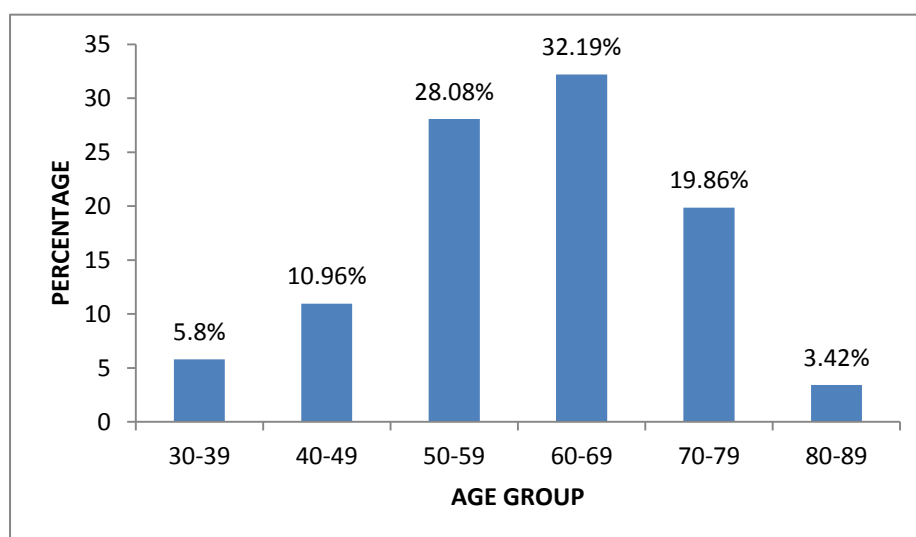
A total of 146 consecutive diabetic patients were selected as per inclusion and exclusion criteria. The demographic details, disease details and overall QOL scores and their subscale values were collected.

6.1 AGE WISE DISTRIBUTION AMONG THE STUDY POPULATION

Among 146 cases, 5.48% (8 patients) were in the age group of 30-39 years, 10.96% (16 patients) were in the age group of 40-49 years, 28.08% (41 patients) were in the age group of 50-59 years, 32.19% (47 patients) were in the age group of 60-69 years, 19.86% (29 patients) were in the age group of 70-79 years and 3.42% (5 patients) were in the age group of 80-89 years. The mean age of the study population was 60.07 ± 11.07 years (range 30-89 years). (Table 1, Figure 1)

**TABLE 1 : AGE WISE DISTRIBUTION AMONG THE STUDY POPULATION
(n=146)**

Age (years)	No of Patients	Percentage
30-39	8	5.48 %
40-49	16	10.96%
50-59	41	28.08%
60-69	47	32.19%
70-79	29	19.86%
80-89	5	3.42%



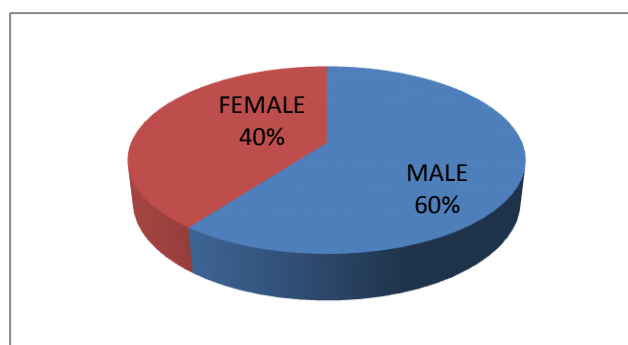
**FIGURE 1 : AGE WISE DISTRIBUTION OF THE STUDY POPULATION
(n=146)**

6.2 GENDER WISE DISTRIBUTION AMONG THE STUDY POPULATION

A total of 146 diabetic patients, males were 60.27% (83 patients) and females were 39.73% (58 patients). ((Table 2, Figure 2)

**TABLE 2 : GENDER WISE DISTRIBUTION AMONG THE STUDY
POPULATION (n=146)**

Gender	Number of Patients	Percentage
MALE	83	60.27 %
FEMALE	58	39.73 %



**FIGURE 2 : GENDER WISE DISTRIBUTION AMONG THE STUDY
POPULATION (n=146)**

6.3 LITERACY AMONG THE STUDY POPULATION

Among 146 patients, 66.44% (97 patients) were literate and 33.56% (49 patients) were illiterate. (Table 3, Figure 3)

TABLE3: LITERACY AMONG THE STUDY POPULATION (n=146)

Literacy	Number of Patients	Percentage
Literate	97	66.44 %
Illiterate	49	33.56 %

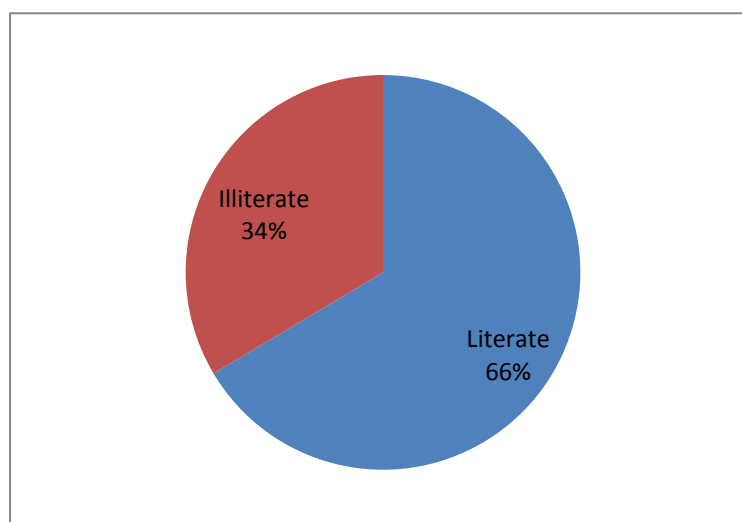


FIGURE 3 – LITERACY AMONG THE STUDY POPULATION (n=146)

6.4 BODY MASS INDEX AMONG THE STUDY POPULATION

A total of 146 patients, 33.56% (49 patients) were in normal body weight, 4.79% (7 patients) were underweight, 54.79% (80 patients) were overweight and 6.85% (10 patients) were obese. (Table 4, Figure 4)

TABLE 4 : BMI AMONG THE STUDY POPULATION (n=146)

BMI	Number of Patients	Percentage
Underweight	7	4.79%
Normal	49	33.56%
Overweight	80	54.79%
Obese	10	6.85%

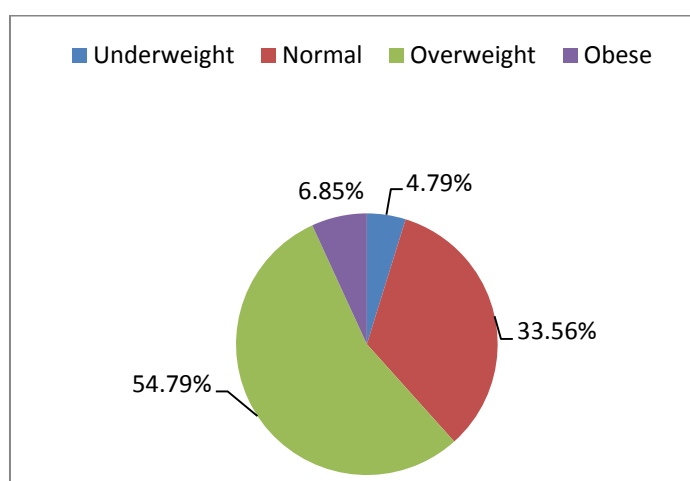


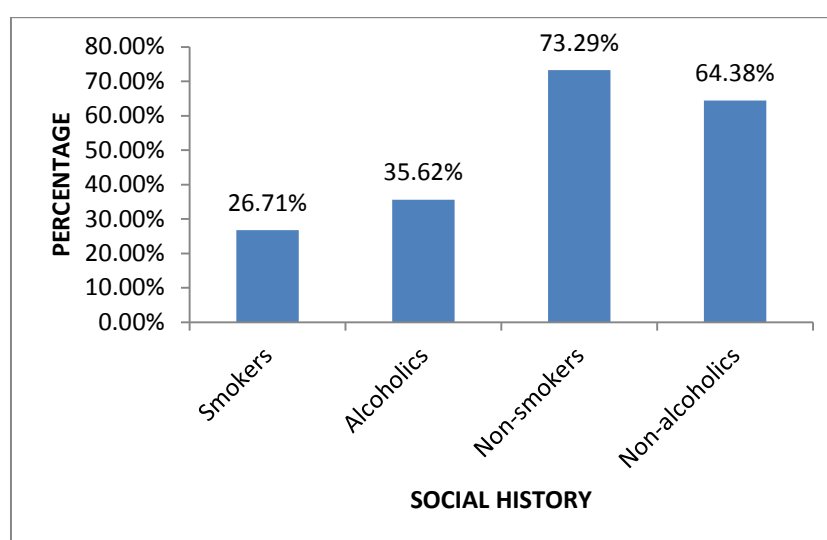
FIGURE 4 : BMI AMONG THE STUDY POPULATION (n=146)

6.5 SOCIAL HISTORY AMONG THE STUDY POPULATION

Among 146 patients, 26.71% (39 patients) were smokers and 73.29% (107 patients) were non smokers whereas 35.62% (52 patients) was having history of alcohol intake and 64.38% (94 patients) was not having history of alcohol intake. (Table 5, figure 5)

TABLE 5: HISTORY OF SMOKING AND ALCOHOL INTAKE AMONG THE STUDY POPULATION (n=146)

History of Smoking And Alcohol Intake	Number of Patients	Percentage
Smokers	39	26.71%
Alcoholic	52	35.62%
Non-smokers	107	73.29%
Non-alcoholic	94	64.38%

**FIGURE 5: HISTORY OF SMOKING AND ALCOHOL INTAKE AMONG THE STUDY POPULATION (n=146)**

6.6 DURATION OF DIABETES MELLITUS AMONG THE STUDY POPULATION

A total of 146 patients, 59.59% (87 patients) were having 6-10 years duration of DM, 15.07% (22 patients) were having 5 years duration of DM, 13.01% (19 patients) were having 11-15 years duration of DM, 5.48% (8 patients) were having 16-20 years duration of DM, 4.11% (6 patients) were having 21-25 years duration of DM, 2.74% (4 patients) were having >25 years duration of DM. Therefore most of the patients were suffering for 6-10 years duration of DM.(Table 6,figure 6)

TABLE 6: DURATION OF DIABETES MELLITUS AMONG THE STUDY POPULATION (n=146)

Duration of Diabetes	Number of Patients	Percentage
5 years	22	15.07%
6-10 years	87	59.59%
11-15 years	19	13.01%
16-20 years	8	5.48%
21-25 years	6	4.11%
>25 years	4	2.74%

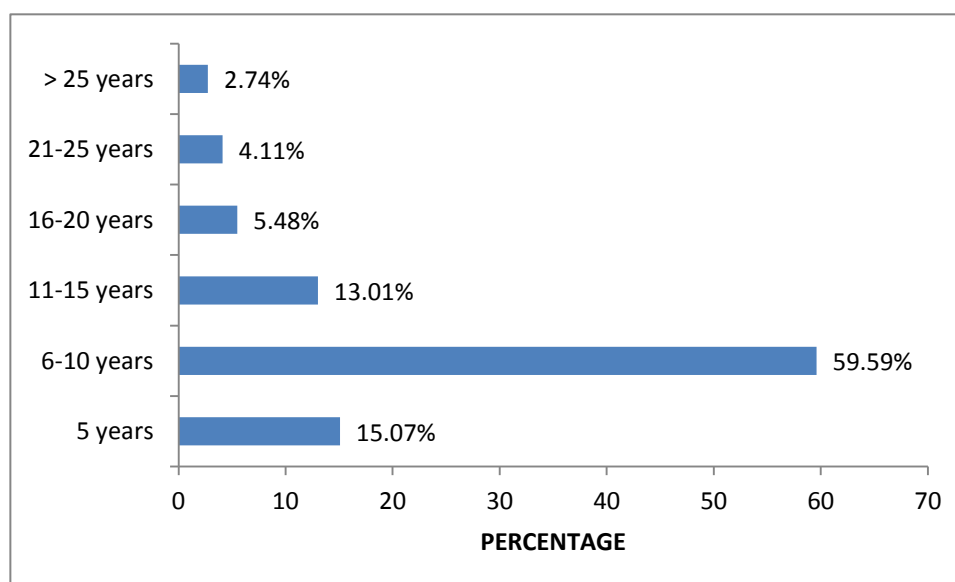


FIGURE 6: DURATION OF DIABETES MELLITUS AMONG THE STUDY POPULATION (n=146)

6.7 PATTERN OF CO-MORBIDITIES PREVALENCE AMONG THE STUDY POPULATION

A total of 146 patients, 36.30% (53 patients) have diabetes mellitus, 41.78% (61 patients) have diabetes mellitus with hypertension, 21.92% (32 patients) have diabetes mellitus with other complications.(Table 7,figure 7)

TABLE 7: PATTERN OF CO-MORBIDITIES PREVALENCE AMONG THE STUDY POPULATION (n=146)

Co-Morbidities	Number of Patients	Percentage
Diabetes Mellitus	53	36.30%
DM + Hypertension	61	41.78%
DM + Others	32	21.92%

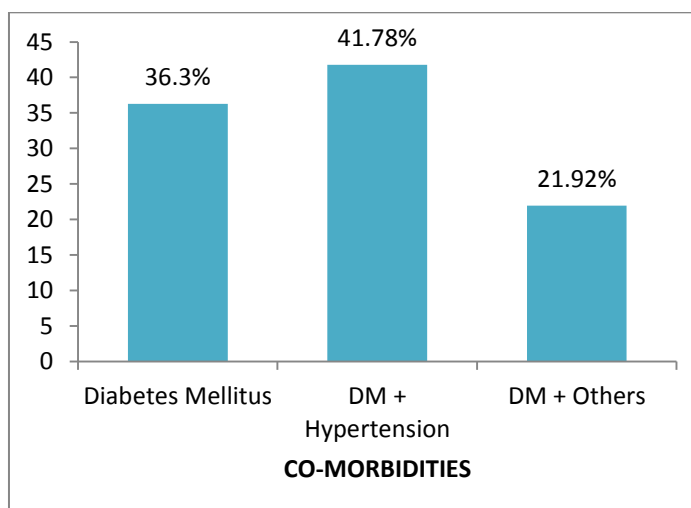


FIGURE 7: PATTERN OF CO-MORBIDITIES PREVALENCE AMONG THE STUDY POPULATION (n=146)

6.8 PREVALENCE OF DIABETIC FOOT ULCER AMONG THE STUDY POPULATION

Among 146 study population, 27.40% (40 patients) have foot ulcer currently remaining 72.60% (106 patients) were without foot ulcer.(Table 8,figure 8)

TABLE 8: PREVALENCE OF DIABETIC FOOT ULCER AMONG THE STUDY POPULATION (n=146)

	Number of Patients	Percentage
Patients with foot ulcer	40	27.40%
Patients without foot ulcer	106	72.60%

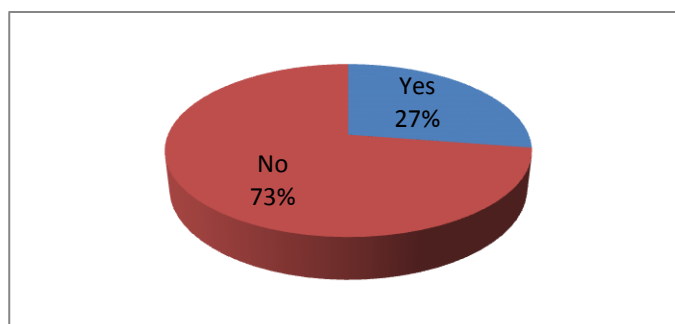


FIGURE 8: PREVALENCE OF DIABETIC FOOT ULCER AMONG THE STUDY POPULATION (n=146)

6.9 AGE WISE DISTRIBUTION OF PATIENTS WHEN FOOT ULCER WAS FOUND

Patients in the age group of 51-60 years(40%) was more susceptible to foot ulcer, the patients within the age group of 61-70 years(37.5%) shows next susceptibility, and comparatively in the age group of 36-50 years it was less. (Table 9, Figure 9)

TABLE 9: AGE WISE DISTRIBUTION OF FOOT ULCER PATIENTS
(n=40)

Age in years	Number of Patients	Percentage
36-50	4	10%
51-60	16	40%
61-70	15	37.5%
>70	5	12.5%

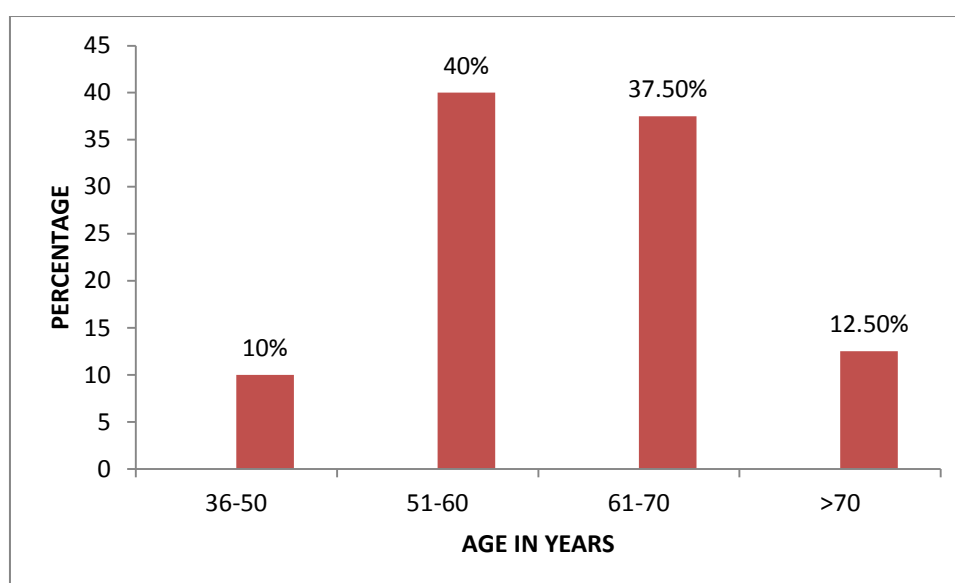


FIGURE 9: AGE WISE DISTRIBUTION OF FOOT ULCER PATIENTS
(n=40)

6.10 TYPES OF TREATMENT IN DIABETIC FOOT ULCER PATIENTS

Among 40 diabetic foot ulcer patients, 52.5% (21 patients) were taking OHA's, (37.5%) 15 patients were taking both OHA's and insulin. Only 10% (4 patients) patients were taking insulin. (Table 10, Figure 10)

TABLE 10: TYPES OF TREATMENT IN DIABETIC FOOT ULCER PATIENTS (n=40)

Types Of Treatment	No of Patients	Percentage
Insulin	4	10%
OHA's	21	52.5%
Both	15	37.5%

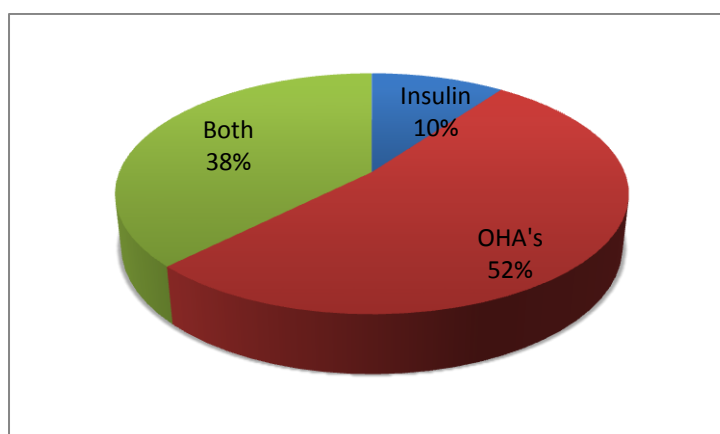


FIGURE 10: TYPES OF TREATMENT IN DIABETIC FOOT ULCER PATIENTS (n=40)

6.11 QUALITY OF LIFE AMONG TYPE 2 DIABETES PATIENTS WITH RESPECT TO DURATION OF DM, TREATMENT REGIMEN AND CO-MORBIDITIES

The mean score of overall quality of life at baseline was 17.44 ± 1.50 and at final follow up was 21.02 ± 2.12 which shows a significant difference among the participants ($p < 0.05$). (Table 11)

TABLE 11: QOL OF LIFE AMONG TYPE 2 DIABETES MELLITUS (n=40)

QOL Domains	Baseline	Follow ups		
		1 st visit	2 nd visit	3 rd visit
Overall QOL	17.44±1.50	18.44±1.18	19.88±1.69	21.02±2.12
Health and Functioning	16.72±1.67	18.41±1.61	20.01±2.09	20.82±1.82
Social and Economical	18.19±2.73	18.74±1.72	19.87±2.29	21.41±1.93
Psychological	18.03±2.36	19.41±2.56	19.94±2.41	21.18±2.96
Family	18.32±3.67	19.1±2.69	20.7±2.99	20.67±2.48

QOL - QUALITY OF LIFE

The mean and standard deviation of overall QOL with respect to the domains of QOL, have a significant ($p \leq 0.05$) for health and functioning, social and economic, psychological/spiritual, and family.

6.12 THE IMPACT OF DURATION OF DM ON HEALTH AND FUNCTIONING DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELLING

The patients having 5-9 years and 10-14 years duration of diabetes shows significant difference ($p < 0.05$) between baseline and follow up 1 in their health and functioning domain after counseling whereas patients ≥ 15 years have no significant improvement ($p > 0.05$) in the first follow up and further education helps them to improve quality of life shows significant difference in follow up 2 and 3. (Table 12, figure 11)

TABLE 12: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON HEALTH AND FUNCTIONING DOMAIN (n=40)

QOL Domains	Duration of DM	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Health and Functioning	5-9 years	16.60 \pm 1.59	18.36 \pm 1.85*	19.94 \pm 2.23*	20.77 \pm 1.85*
	10-14 years	16.44 \pm 1.38	18.5 \pm 1.06*	19.68 \pm 1.72*	20.52 \pm 1.95*
	≥ 15 years	17.54 \pm 2.07	18.13 \pm 1.64 ^{ns}	20.82 \pm 2.07*	21.51 \pm 1.21*

* $P < 0.05$, ns-not significant

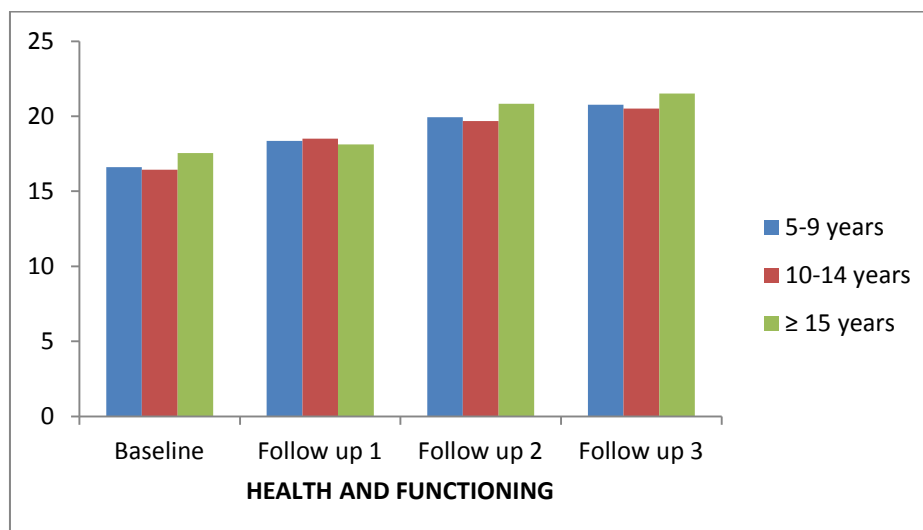


FIGURE 11: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON HEALTH AND FUNCTIONING DOMAIN (n=40)

6.13 THE IMPACT OF DURATION OF DM ON SOCIAL AND ECONOMICAL DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELLING

In social and economical domain, there were no significant differences between baseline and follow up 1 in patients having duration of DM for 5-9 years. After the second counseling, There was a significant difference ($p < 0.05$). 10-14 years duration of DM patients shows significance only after third counseling. The patients having more than 15 years of DM were not significant socially and economically ($p > 0.05$). Finally, 5-9 years duration of DM patients have better quality of life when compared to others. (Table 13, figure 12)

TABLE 13: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON SOCIAL AND ECONOMICAL DOMAIN (n=40)

QOL Domains	Duration of DM	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Social and Economical	5-9 years	17.42±2.72	18.57±1.50 ^{ns}	19.81±2.35*	21.17±1.90*
	10-14 years	18.54±2.31	18.94±1.78 ^{ns}	19.75±2.52 ^{ns}	21.42±1.66*
	≥15 years	19.76±2.66	18.82±2.13 ^{ns}	20.25±1.43 ^{ns}	22.10±2.27 ^{ns}

*P<0.05, ns-not significant

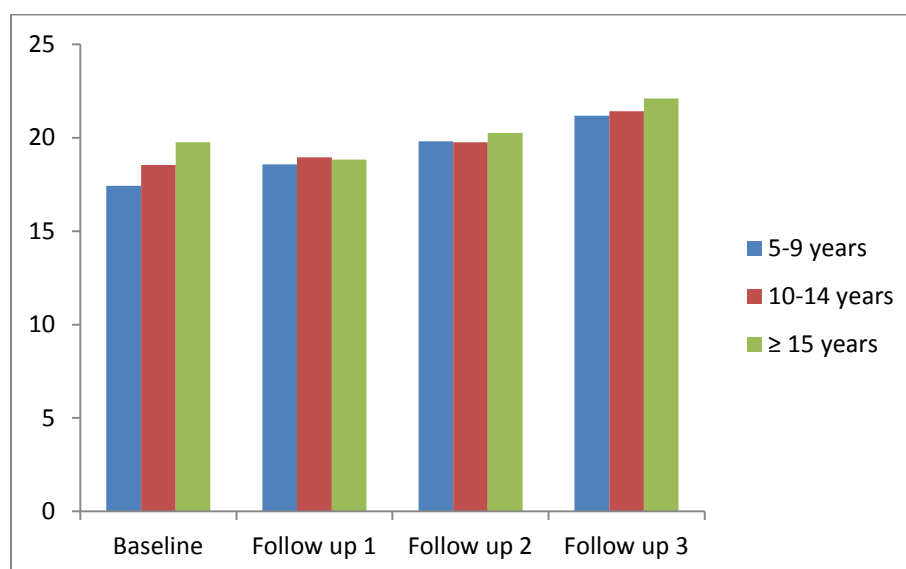


FIGURE12: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON SOCIAL AND ECONOMICAL DOMAIN (n=40)

6.14 THE IMPACT OF DURATION OF DM ON PSYCHOLOGICAL AND SPIRITUAL DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELLING

The patients with 5-9 years duration of DM have no significant difference in follow up 1 ($p > 0.05$). But after counseling, there shows a

difference in significance ($p < 0.05$). 10-14 years duration had significant difference in their psychological domain only at the follow up 3 ($p < 0.05$). The mean values obtained for the patients having ≥ 15 years duration of DM was not significant in all the three follow ups. (Table 14, Figure 13)

TABLE 14: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON PSYCHOLOGICAL AND SPIRITUAL DOMAIN (n=40)

QOL Domains	Duration of DM	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Psychological/ Spiritual	5-9 years	17.66 \pm 2.23	20.17 \pm 2.54 ^{ns}	20.52 \pm 2.14*	20.51 \pm 3.29*
	10-14 years	18.16 \pm 2.38	18.64 \pm 2.33 ^{ns}	19.01 \pm 2.66 ^{ns}	20.83 \pm 2.26*
	≥ 15 years	18.84 \pm 2.48	18.66 \pm 2.36 ^{ns}	20.01 \pm 2.09 ^{ns}	21.92 \pm 2.23 ^{ns}

* $P < 0.05$, ns-not significant

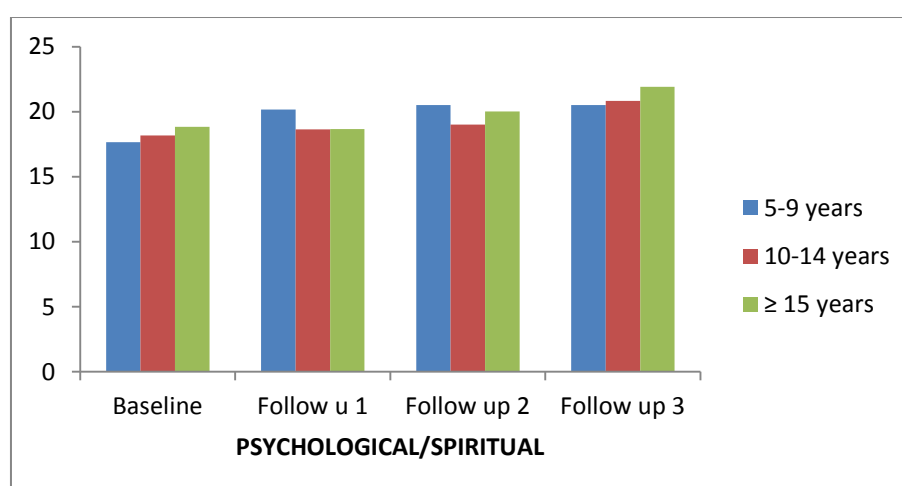


FIGURE 13: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON PSYCHOLOGICAL / SPIRITUAL DOMAIN (n=40)

6.15 THE IMPACT OF DURATION OF DM ON FAMILY DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

5-9 years duration of DM patients had no significant changes over follow up 1 ($p > 0.05$) and after second counseling, the patient shows significant changes over follow up 2 which indicates the improvement of quality of life in the family domain. The patients with 10-14 years of DM does not have significance till the second follow up whereas after educating them for second time shows significant difference in their follow up 3 ($p < 0.05$). The patients having ≥ 15 years duration of DM shows no significant differences in all the three follow ups ($p > 0.05$). (Table 15, figure 14)

TABLE 15: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON FAMILY DOMAIN (n=40)

QOL Domains	Duration of DM	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Family	5-9 years	17.50 \pm 3.38	18.70 \pm 2.51 ^{ns}	20.83 \pm 2.96*	20.79 \pm 2.24*
	10-14 years	18.32 \pm 3.54	20.52 \pm 2.4 ^{ns}	20.03 \pm 2.71 ^{ns}	19.85 \pm 2.88*
	≥ 15 years	20.67 \pm 3.72	20.54 \pm 2.73 ^{ns}	21.57 \pm 3.28 ^{ns}	21.83 \pm 1.64 ^{ns}

* $P < 0.05$, ns-not significant

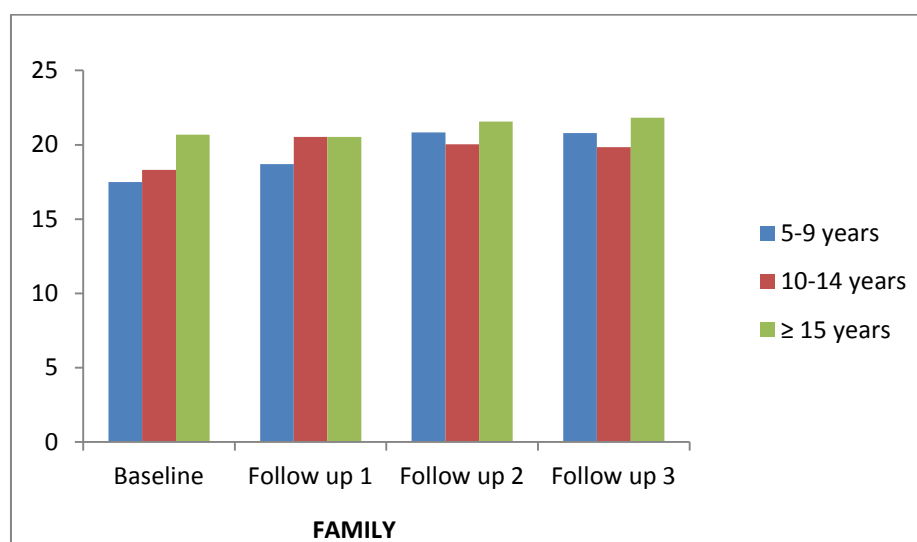


FIGURE 14: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON FAMILY DOMAIN (n=40)

6.16 THE IMPACT OF TREATMENT REGIMEN ON HEALTH AND FUNCTIONING DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELLING

The patients with all types of treatment shows significant improvement over health and functioning domain in all the follow ups with baseline. This result shows that their medication adherence is good and moreover counseling helped them in the aspect of managing the medication compliance (Table 16,figure 15)

TABLE 16: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON HEALTH AND FUNCTIONING DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Health and Functioning	Insulin	15.38±0.48	17.88±0.72*	21.05±2.41*	20.87±1.97*
	OHA's	17.12±1.93	18.89±1.81*	19.58±1.95*	20.84±2.03*
	Both	16.50±1.17	17.88±1.21*	20.34±2.03*	20.79±1.44*

*P<0.05, ns-not significant

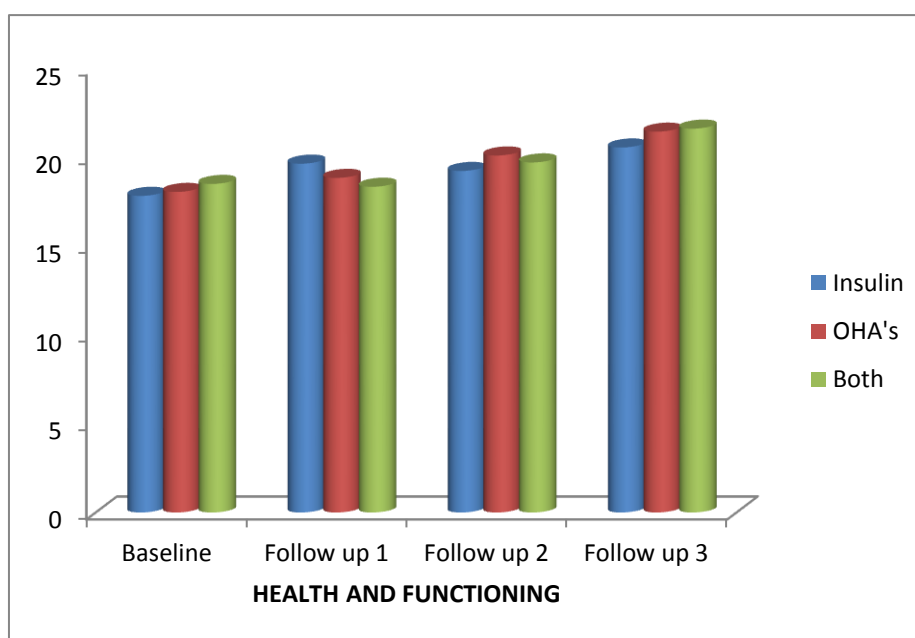


FIGURE 15: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON HEALTH AND FUNCTIONING DOMAIN (n=40)

6.17 THE IMPACT OF TREATMENT REGIMEN ON SOCIAL AND ECONOMICAL DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

Patients were on all the types of treatment does not show significant improvement over social and economical domain in their follow up 1 ($p > 0.05$) whereas in their further follow ups they show a gradual significant differences in their social life ($p < 0.05$). (Table 17, Figure 16).

TABLE 17: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON SOCIAL AND ECONOMICAL DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Social and Economical	Insulin	17.83±2.44	19.64±1.81 ^{ns}	19.23±1.79*	20.55±1.49*
	OHA's	18.05±2.95	18.84±1.64 ^{ns}	20.10±2.21*	21.44±1.82*
	Both	18.50±2.43	18.34±1.85 ^{ns}	19.71±2.46*	21.61±2.12*

* $P < 0.05$, ns-not significant

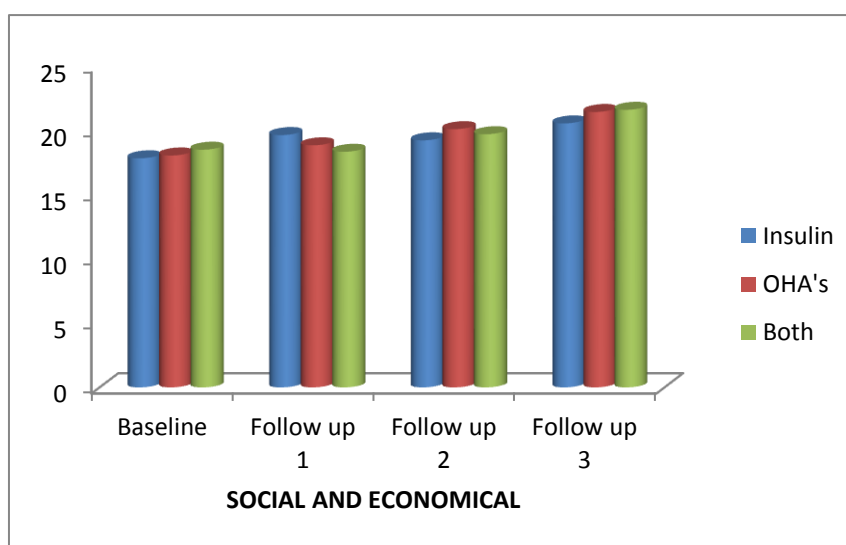


FIGURE 16: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON SOCIAL AND ECONOMICAL DOMAIN (n=40)

6.18 THE IMPACT OF TREATMENT REGIMEN ON PSYCHOLOGICAL OR SPIRITUAL DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

The insulin taking patients does not show any significant difference between baseline and follow up 1. The patients were counseled for second time and in their third follow up the significant difference was seen ($p < 0.05$). Patients taking OHAs shows their significance after three counseling, there was an improvement in their QOL. The patients taking both insulin and OHA's shows significant differences between baseline and follow up 2, final follow up. (Table 18, figure 17)

TABLE 18: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON PSYCHOLOGICAL /SPIRITUAL DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Psychological/ Spiritual	Insulin	16.86±3.28	20.05±1.76 ^{ns}	21.37±0.56*	23.07±3.03*
	OHA's	18.59±2.12	19.68±2.47 ^{ns}	19.61±1.78 ^{ns}	21.34±2.73*
	Both	17.56±2.18	18.86±2.75 ^{ns}	20.01±3.20*	20.46±2.83*

* $P < 0.05$, ns-not significant

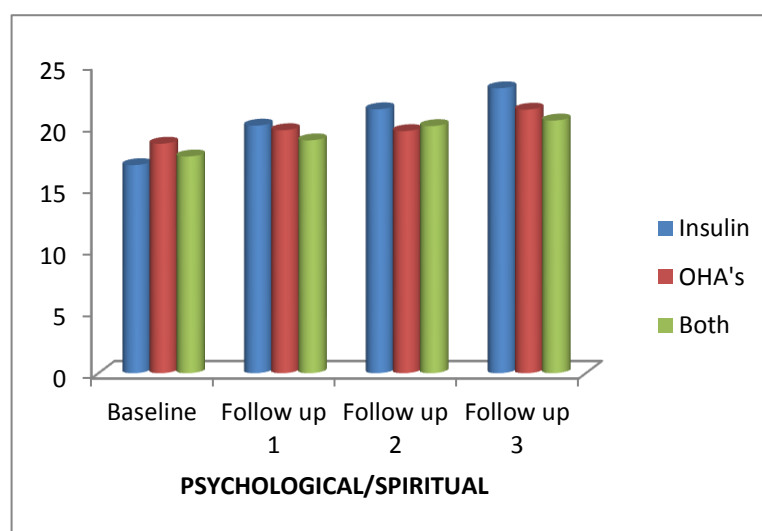


FIGURE 17: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON PSYCHOLOGICAL/SPIRITUAL DOMAIN (n=40)

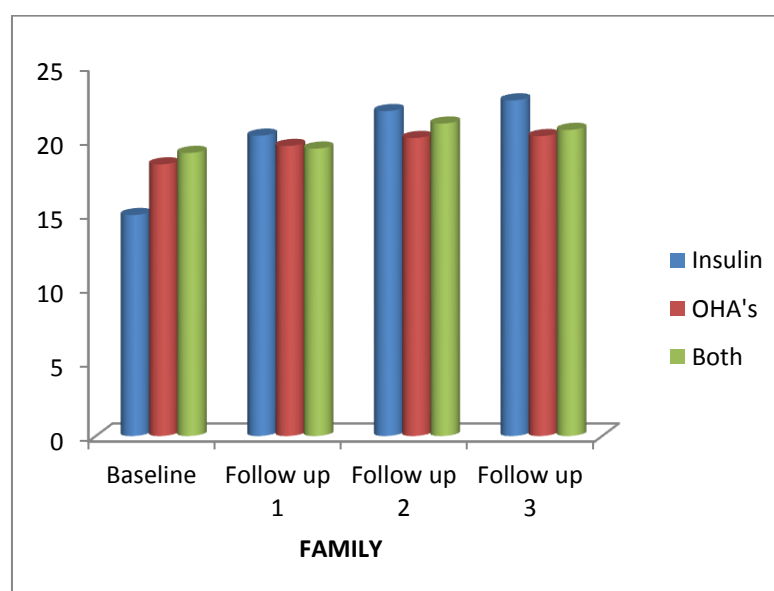
6.19 THE IMPACT OF TREATMENT REGIMEN ON FAMILY DOMAIN BY COMPARISON OF MEAN AFTERPATIENTCOUNSELING

The patients were on insulin treatment shows significant improvement compared to other types of treatment ($p < 0.05$). Patients taking OHA's or both the medication does not have significant improvement in their family domain ($p > 0.05$). Therefore in this study, insulin taking patients have good family support than others. (Table 19, Figure 18)

**TABLE 19 : COMPARISON OF EFFECT OF PATIENT COUNSELLING ON
FAMILY DOMAIN (n=40)**

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Family	Insulin	14.96±0.92	20.3±2.10*	21.96±3.19*	22.68±2.19*
	OHA's	18.37±3.44	19.61±2.73 ^{ns}	20.15±3.10 ^{ns}	20.27±2.51 ^{ns}
	Both	19.14±3.95	19.43±2.79 ^{ns}	21.12±2.57 ^{ns}	20.69±2.23 ^{ns}

*P<0.05, ns-not significant



**FIGURE 18: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON
FAMILY DOMAIN (n=40)**

6.20 THE IMPACT OF CO-MORBIDITIES ON HEALTH AND FUNCTIONING DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

Though the patients having co-morbidities their health and functioning remains same as the patients without having co-morbidities. The counseling has done for the patients have less attitude towards their physical strength. There was a significant difference between baseline and all the three follow ups ($p < 0.05$). (Table 20, Figure 19)

TABLE 20: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON HEALTH AND FUNCTIONING DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Health and Functioning	With comorbidities	16.05±1.19	18.27±1.82*	19.74±2.26*	20.09±1.19*
	Without comorbidities	17.21±1.80	18.52±1.42*	20.21±1.93*	21.36±2.01*

*P<0.05, ns-not significant

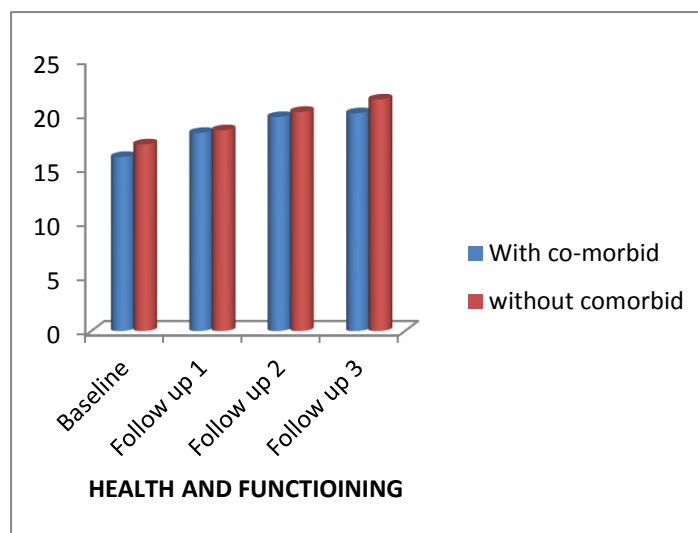


FIGURE 19: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON HEALTH AND FUNCTIONING DOMAIN (n=40)

6.21 THE IMPACT OF CO-MORBIDITIES ON SOCIAL AND ECONOMICAL DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

Those patients having co-morbidities have no significant differences among their follow ups 1 and 2 with baseline values ($p > 0.05$) whereas in third follow up there was a significant improvement in their social and economical subscale values indicates quality of life was improved in their social life. No co-morbid patients shows significant improvement on their first follow up itself ($p < 0.05$).

TABLE 21: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON SOCIAL AND ECONOMICAL DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Social and Economical	With comorbidities	18.01±2.54	18.82±1.90 ^{ns}	19.00±1.43 ^{ns}	20.99±1.71*
	Without comorbidities	18.32±2.85	18.67±1.58 ^{ns}	20.51±2.57*	21.73±2.02*

*P<0.05, ns-not significant

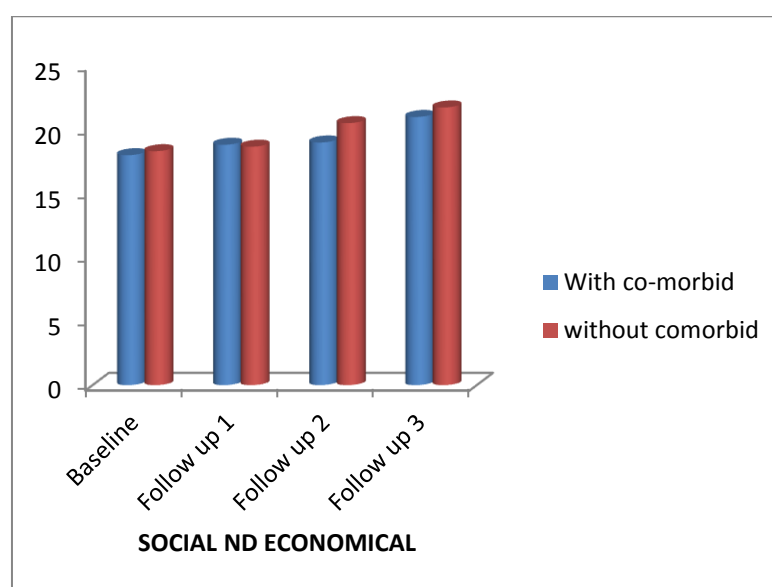


FIGURE 20: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON SOCIAL AND ECONOMICAL DOMAIN (n=40)

6.22 THE IMPACT OF CO-MORBIDITIES ON PSYCHOLOGICAL OR SPIRITUAL DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

The patients with co-morbid conditions shows their significant difference only after third counseling i.e in final follow up they shows their significant improvement in psychological domain. The diabetic patients with no co-morbid conditions seems better quality of life compared to the patients having co-morbid conditions.

TABLE 22: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON PSYCHOLOGICAL/SPIRITUAL DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Psychological/ Spiritual	With comorbidities	17.99±2.58	18.64±2.50 ^{ns}	19.38±2.23 ^{ns}	21.34±2.45*
	Without comorbidities	18.06±2.19	19.98±2.45*	20.35±2.45*	21.07±3.18*

*P<0.05, ns-not significant

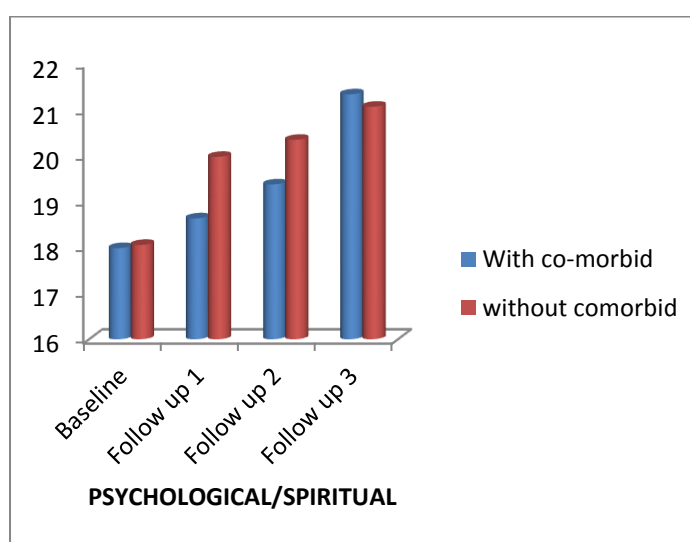


FIGURE 21: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON PSYCHOLOGICAL/SPIRITUAL DOMAIN (n=40)

6.23 : THE IMPACT OF CO-MORBIDITIES ON FAMILY DOMAIN BY COMPARISON OF MEAN AFTER PATIENT COUNSELING

The impact of co-morbidities on family domain shows that family support is high in those patients having co-morbid conditions. Therefore, significant differences seen in all the follow ups whereas the patient without co-morbid conditions shows significant improvement ($p < 0.05$) in their follow up 1 and final follow up.

TABLE 23: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON FAMILY DOMAIN (n=40)

QOL Domains	Items	Baseline	Follow ups		
			1 st visit	2 nd visit	3 rd visit
Family	With comorbidities	18.14±3.27	20.62±2.74*	20.78±3.22*	21.25±2.21*
	Without comorbidities	18.45±3.94	18.87±2.39 ^{ns}	20.64±2.81*	20.23±2.58 ^{ns}

*P<0.05, ns-not significant

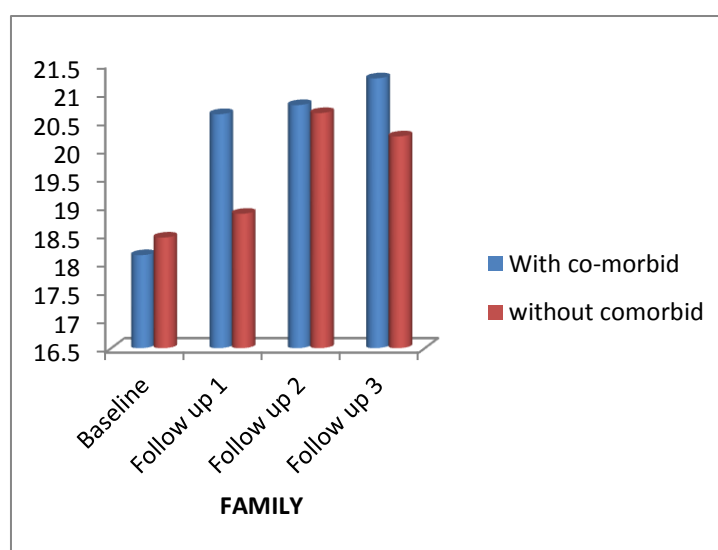


FIGURE 22: COMPARISON OF EFFECT OF PATIENT COUNSELLING ON FAMILY DOMAIN (n=40)

7. DISCUSSION

The pharmacist involvement in diabetes care is justified by his or her position as a key member of the health care team. He or she needs to work together with other health professionals to prevent diabetes and its complications.

The study comprised of 146 patients, out of which, most patients were in the age group of 60-69 years. In this study, the male patients (60%) were more predominant in number than the female patients. A study conducted by Bedilu Deribe et al. showed the mean age of the study population was 50.72 ± 13.39 years. With regard to gender distribution 59.7% were males.⁽¹²⁾

A study conducted by Adepu Ramesh et al. shows that majority of the patients were having normal body mass index. In present study majority of the patients were overweight (54.79%).⁽²³⁾

In this study, out of 146 diabetic patients attended hospital, 27.40% were having foot ulcer. A cross sectional study carried out by Kahsu Gebrekirstos et al. found that 12% were having foot ulcer. Another study conducted by Bedilu Deribe et al, observed 14.8% foot ulcer patients among 216 diabetic patients.^(10,12)

In present study 93 patients has comorbidities where the DM with hypertensive patients was high (41.78%). A study conducted by M. Porojan et al. reported that 83.3% of the diabetic participants has co-morbid diseases and the most commonly reported disease was hypertension (46.1%) followed by hyperlipidemia (6.1%). Another study conducted by Elham Ghasemi et al. findings shows comorbidity was frequent (96%). Similar study conducted by Anumol Mathew et al shows 63% of subjects had co-morbid illness.^(6,50,68)

When this overall quality of life score was broken down into four subscales would became apparent that the respondents were least satisfied

with their health followed by their social and economic aspects and were most satisfied with their psychological/spiritual aspects followed by family aspects.

In the analysis of the impact of diabetes on QOL for different domains, the greatest negative impact of T2DM with ≥ 15 years duration and oral hypoglycemic agents was observed. M. Porojan et al. conducted a study and their result shows that the duration of diabetes and insulin therapy had a significant impact on life quality among the diabetic patients.⁽⁵⁰⁾

In this study, patients with oral hypoglycemic agents have less quality of life than who were on insulin, and both medication. Abuawad Majed S. S et al. found that patients who were on oral hypoglycemic agents (OHAs) only had a better HRQOL than who were on insulin, but this difference did not reach the significant level for longer duration of DM (> 10 years).⁽⁷¹⁾

In this study, the effect of insulin does not affect the Quality of life of patients compared to other types of treatment. M. Porojan et al. examining the effects of insulin use and QOL, there are no significant differences between patients following insulin therapy and patients with other therapeutic protocols.⁽⁵⁰⁾

Based on the findings, participants had average levels of QOL. These findings showed that QOL in type 2 diabetes mellitus patients needs improvement through educating the patients regarding their disease condition.

The present study has the patient without comorbidities shows better quality of life when compared to patients have co-morbid condition. Results also agreed with the study Abuwad S.S. Majed et al., found that patients who did not develop any complications had better means of the QOL domains than those who had only one complication.⁽⁷¹⁾

The present study has the patient without comorbidities shows better quality of life when compared to patients have co-morbid condition. Results also agreed with the study Abuwad S.S. Majed et al., found that patients who

did not develop any complications had better means of the QOL domains than those who had only one complication. ⁽⁷¹⁾

Abuwad S.S. Majed et al., results in the effect of the treatment of DM on the QOL, that the means of all QOL domains for diabetic patients who were treated by OHAs were slightly better than those who were treated by Insulin. ⁽⁷¹⁾

These results are in conflict with the research that has shown increasing treatment intensity in patients with type II DM from diet and exercise alone, to oral medications, to insulin, is associated with worsening QOL, Rubin and Peyrot et al. ⁽⁷⁰⁾

In this study patients with insulin therapy shows better quality of life than patients were on OHA's. In regard to the type of insulin therapy, Chantelau et al. studied in two patient groups. In cohort A, intensified their traditional insulin injection with syringe to injections with insulin-pen. In cohort B, changed from intensive therapy with pen to insulin pump-treatment. Treatment satisfaction increased after intensification of insulin therapy in both groups, due to greater flexibility with leisure-time activities, and with the diet. ⁽⁶⁹⁾

Regarding the duration of DM and QOL, Directly after diagnosis, the patients suffered from the psychological shock and they were not able to accept or adapt to the new situation; this is why their QOL values decreased in the first years of diagnosis. But after 5 years, they started to psychologically accept the condition and adapt to their disease and manage it correctly, as a result, their QOL means had improved. Finally, when DM extends to more than 10 years and the patients started to develop complications.

8. CONCLUSION

The prevalence of diabetic patients have foot ulcer was 27.40%. The patients with mean age group of 55.5 ± 03.03 years were more prone to the diabetic foot ulcer.

The present study concludes that participants had average levels of overall quality of life. The quality of life could be improved through the patient education regarding their disease condition and drugs used. The main factors associated with poor QOL were duration of diabetes mellitus and co-morbid conditions.

The psychological domain of quality of life was most affected significantly for the patients having longer duration of disease condition particularly for the patients with more than 15 years of diabetes mellitus.

As per the study, with regular patient counseling maintenance of diet and exercise with good patient compliance improves the quality of life of patients in day-to-day activities and that has reduced the morbidity and mortality rate. Educating the patient is an important aspect to prevent the disease and promote the health of the individuals.

The diabetes have an adverse effect on the quality of life of the patients. The study suggested that the regular medication, creating self-help groups, physical activity, good glycemic control may help to improve the quality of life.

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VIVEKANANDHA MEDICAL CARE HOSPITAL

SPONSORED BY : ANGAMMAL EDUCATIONAL TRUST.

Elayampalayam - 637 205. Tiruchengode, Namakkal Dt., Tamil Nadu.

Phone : 04288 - 234677, 94890 59111, FAX : 04288 - 234676, Emergency : 04288 - 234108.

Website : www.vivekanandha.ac.in email : vivekanandhamedicalcare@gmail.com

Ref No: SVCPIEC/JUL/2016/07

Date: 06.07.2016

To

P.Parkavi Rani,
II- M.Pharm Pharmacy Practice,
Swamy Vivekanandha College of Pharmacy,
Elayampalayam, Tiruchengode – 637205.

Sub: Approval of the Study Protocol – Reg

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "A STUDY ON PREVALENCE OF DIABETIC FOOT ULCER AND QUALITY OF LIFE OF TYPE 2 DIABETES MELLITUS PATIENTS IN A MULTI SPECIALITY HOSPITAL" under the guidance of Dr. T. Tamilselvan on 15.06.2016.

The following documents were reviewed:

- Study protocol
- Patient Information Sheet and Informed Consent Form
- Study data collection form
- Principal Investigator's /Co-PI Current CV
- Investigator's undertaking

The following members of the ethics committee were present at the meeting held on 15.06.2016 at Vivekanandha Medical Care Hospital.

- Dr. Sathish K M - Chairman
- Dr. A. Palanisamy - Member Secretary
- Dr. T. Poovendran - Member
- Dr. S.Ananda Thangadurai - Member
- Dr. V. Vinoth Prabhu - Member

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee to be informed about the progress of the study, any serious adverse events occurring in the course of the study, any changes in the protocol and patient information/informed consent and to provide a copy of the final report on completion.

Dr. A. Palanisamy

Member Secretary,
Institutional Ethics Committee
Swamy Vivekanandha College of Pharmacy,
Elayampalayam-637 205,
Tiruchengode Tk, Tamil Nadu.

Study Volunteer ID:
Study Volunteer Name:

**Swamy Vivekanandha College of Pharmacy
Institutional Human Ethics Committee
INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS**

(strike off items that are not applicable)

I, Parkavi Rani.P Am carrying out a study on the topic: **A study on Prevalence of Diabetic Foot Ulcer and Quality of Life of Type 2 Diabetes Mellitus Patients in a Multi specialty Hospital.**

as part of my / our research project being carried out under the aegis of the Department of: **Pharmacy Practice**
my research guide is: **DR. T. TAMIL SELVAN**

The justification for this study is: **Predicts an Individual's capacity to manage his disease and maintain long term health and wellbeing.**

The objectives of this study are:

Primary Objective: **To assess the prevalence of diabetic foot ulcer**

Secondary Objective: **To evaluate the quality of life in type 2 diabetes mellitus patients**

Sample size: 150 patients (app)

Study volunteers / participants are (specify population group & age group): **Patients with type 2 DM of age ≥30 years**

Location: **Vivekanandha medical care hospital**

We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Initial interview (specify approximate duration): **10-15** minutes.

Data collected will be stored for a period of fifteen years. We will / will not use the data as part of another study.

Health education sessions: Number of sessions: **3**. Approximate **duration** of each session: **15** minutes.

Clinical examination (Specify details and purpose): **NA**

Blood sample collection: Specify quantity of blood being drawn: _____ml.

No. of times it will be collected: _____.

Whether blood sample collection is part of routine procedure or for research (study) purpose:

1. Routine procedure 2. Research purpose

Specify **purpose**, discomfort likely to be felt and side effects, if any: _____

Whether blood sample collected will be stored after study period: Yes / No, it will be destroyed

Study Volunteer ID:
Study Volunteer Name:

Whether blood sample collected will be sold: Yes / No

Whether blood sample collected will be shared with persons from another institution: Yes / No

Medication given, if any, duration, side effects, purpose, benefits:

Whether medication given is part of routine procedure: Yes / No (If not, state reasons for giving this medication)

Whether alternatives are available for medication given: Yes / No (If not, state reasons for giving this particular medication)

Final interview (specify approximate duration): 15 mts. If **photograph** is taken, purpose:

Benefits from this study: **To increase the quality of life among type 2 diabetic patients.**

Risks involved by participating in this study: **NIL**

How the **results** will be used:

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, **you have the right to withdraw from the interview / study at anytime.** You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered nor would it attract any penalty. You will continue to have access to the regular services offered to a patient. You will **NOT** be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings - including adverse events, if any, – whether directly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation.

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI: 08012291431

ஓப்புதல் படிவம்

தேதி:

----- ஆகியநான், VMCH மருத்துவமனையில் -----
----- துறையின் கீழ், -----

--- என்றதலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வுவழிகாட்டி:

ஆய்வு மேற்கொள்வதற்கான அடிப்படை:

ஆய்வின் நோக்கம்:

ஆய்வு மேற்கொள்ளும் இடம்:

ஆய்வின் பலன்கள்:

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் ----- வருடங்கள் பாதுகாக்கப்படும்.
இவை வேறு எந்த ஆய்விற்கும் பயன்படுத்தப் படமாட்டாது. எந்த நிலையிலும் உங்களைப்
பற்றிய தகவல்கள் யாருக்கும் தெரிவிக்கப்படமாட்டாது. அவை
இரகசியமாக வைக்கப்படும்.

இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்ளுவதால் எந்த விதமான பலனும்
உங்களுக்குக் கிடைக்காது. எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்
கொள்ளும் உரிமை உங்களுக்கு உண்டு.

ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சையில்
எந்த வித மாற்றமும் இருக்காது.

இந்த ஆராய்ச்சிக்காக உங்களிடம் சில கேள்விகள் கேட்கப்படும் / சில இரத்த மாதிரிகள் அல்லது திசு மாதிரிகள் எடுக்கப்படும்.

மேலும், இந்த ஆய்வில் பங்கு கொள்வது உங்கள் சொந்த விருப்பம். இதில் எந்த விதக் கட்டாயமும் இல்லை. நீங்கள் விருப்பப்பட்டால், இந்த ஆய்வின் முடிவுகள் உங்களுக்குத் தெரியப்படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம் :

தேதி :

ஆய்வுக்குட்படுவரின் ஒப்புதல்:

நான் இந்தஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்பாட்டினைப் பற்றிதெளிவாகவும்,விளக்கமாகவும் தெரியப்படுத்தப் பட்டுள்ளேன். இந்தஆராய்ச்சியில் பங்குகொள்ளவும், இந்தஆராய்ச்சியின் மருத்துவரீதியானகுறிப்புகளைவரும் காலத்திலும் உபயோகப்படுத்திக் கொள்ளவும் முழு மனதுடன் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுவரின் பெயர்,முகவரி :

கையொப்பம் :

தேதி :

DATA ENTRY FORM

NAME

IP NO/OP NO

AGE /SEX

DOA

HEIGHT

WEIGHT

BMI

MARITAL STATUS

EDUCATIONAL STATUS

OCCUPATION

REASON FOR ADMISSION

PAST MEDICAL HISTORY

TYPE OF DIABETES

DURATION OF DIABETES

PAST MEDICATION HISTORY

FAMILY HISTORY

SOCIAL HABITS

SMOKER

TOBACCO

ALCOHOLIC

NONE

BLOOD GLUCOSE PROFILE

DATE	I VISIT	II VISIT	III VISIT
FBS(60-90)			
RBS(90-110)			
PPBS(80-150)			

DIABETIC FOOT SCREENING:

RIGHT FOOT

LEFT FOOT

DURATION OF ULCER

SIZE OF ULCER

DIAGNOSIS

OTHERS

TREATMENT

Ferrans and Powers
QUALITY OF LIFE INDEX®
DIABETES VERSION - III

PART 1. For each of the following, please choose the answer that best describes how satisfied you are with that area of your life. Please mark your answer by circling the number. There are no right or wrong answers.

HOW SATISFIED ARE YOU WITH:	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. The amount of energy you have for everyday activities?	1	2	3	4	5	6
4. Your ability to take care of yourself without help?	1	2	3	4	5	6
5. Your ability to control your blood sugar?	1	2	3	4	5	6
6. The changes you have had to make in your life because of diabetes (such as diet, exercise, taking insulin or diabetes pill, checking blood sugar)?	1	2	3	4	5	6
7. The amount of control you have over your life?	1	2	3	4	5	6
8. Your chances of living as long as you would like?	1	2	3	4	5	6
9. Your family's health?	1	2	3	4	5	6
10. Your children?	1	2	3	4	5	6
11. Your family's happiness?	1	2	3	4	5	6
12. Your sex life?	1	2	3	4	5	6
13. Your spouse, lover, or partner?	1	2	3	4	5	6
14. Your friends?	1	2	3	4	5	6
15. The emotional support you get from your family?	1	2	3	4	5	6

(Please Go To Next Page)

HOW *SATISFIED* ARE YOU WITH:

	Very Dissatisfied	Moderately Dissatisfied	Slightly Dissatisfied	Slightly Satisfied	Moderately Satisfied	Very Satisfied
16. The emotional support you get from people other than your family?	1	2	3	4	5	6
17. Your ability to take care of family responsibilities?	1	2	3	4	5	6
18. How useful you are to others?	1	2	3	4	5	6
19. The amount of worries in your life?	1	2	3	4	5	6
20. Your neighborhood?	1	2	3	4	5	6
21. Your home, apartment, or place where you live?	1	2	3	4	5	6
22. Your job (if employed)?	1	2	3	4	5	6
23. Not having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
24. Your education?	1	2	3	4	5	6
25. How well you can take care of your financial needs?	1	2	3	4	5	6
26. The things you do for fun?	1	2	3	4	5	6
27. Your chances for a happy future?	1	2	3	4	5	6
28. Your peace of mind?	1	2	3	4	5	6
29. Your faith in God?	1	2	3	4	5	6
30. Your achievement of personal goals?	1	2	3	4	5	6
31. Your happiness in general?	1	2	3	4	5	6
32. Your life in general?	1	2	3	4	5	6
33. Your personal appearance?	1	2	3	4	5	6
34. Yourself in general?	1	2	3	4	5	6

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PART 2. For each of the following, please choose the answer that best describes how **important** that area of your life is to you. Please mark your answer by circling the number. There are no right or wrong answers.

	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
HOW IMPORTANT TO YOU IS:						
1. Your health?	1	2	3	4	5	6
2. Your health care?	1	2	3	4	5	6
3. Having enough energy for everyday activities?	1	2	3	4	5	6
4. Taking care of yourself without help?	1	2	3	4	5	6
5. Controlling your blood sugar?	1	2	3	4	5	6
6. The changes you have had to make in your life because of diabetes (such as diet, exercise, taking insulin or diabetes pill, checking blood sugar?	1	2	3	4	5	6
7. Having control over your life?	1	2	3	4	5	6
8. Living as long as you would like?	1	2	3	4	5	6
9. Your family's health?	1	2	3	4	5	6
10. Your children?	1	2	3	4	5	6
11. Your family's happiness?	1	2	3	4	5	6
12. Your sex life?	1	2	3	4	5	6
13. Your spouse, lover, or partner?	1	2	3	4	5	6
14. Your friends?	1	2	3	4	5	6
15. The emotional support you get from your family?	1	2	3	4	5	6
16. The emotional support you get from people other than your family?	1	2	3	4	5	6

(Please Go To Next Page)

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HOW <i>IMPORTANT</i> TO YOU IS:	Very Unimportant	Moderately Unimportant	Slightly Unimportant	Slightly Important	Moderately Important	Very Important
17. Taking care of family responsibilities?	1	2	3	4	5	6
18. Being useful to others?	1	2	3	4	5	6
19. Having no worries?	1	2	3	4	5	6
20. Your neighborhood?	1	2	3	4	5	6
21. Your home, apartment, or place where you live?	1	2	3	4	5	6
22. Your job (if employed)?	1	2	3	4	5	6
23. Having a job (if unemployed, retired, or disabled)?	1	2	3	4	5	6
24. Your education?	1	2	3	4	5	6
25. Being able to take care of your financial needs?	1	2	3	4	5	6
26. Doing things for fun?	1	2	3	4	5	6
27. Having a happy future?	1	2	3	4	5	6
28. Peace of mind?	1	2	3	4	5	6
29. Your faith in God?	1	2	3	4	5	6
30. Achieving your personal goals?	1	2	3	4	5	6
31. Your happiness in general?	1	2	3	4	5	6
32. Being satisfied with life?	1	2	3	4	5	6
33. Your personal appearance?	1	2	3	4	5	6
34. Are you to yourself?	1	2	3	4	5	6

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Items for Subscales for the Quality of Life Index (QLI) – Diabetes III Version

Five scores are calculated for the Ferrans and Powers Quality of Life Index: (1) Total Quality of Life Score (2) Health and functioning subscale score, (3) Social and economic subscale score, (4) Psychological/spiritual subscale score, and (5) Family subscale score. Items listed below are from both Part 1 (Satisfaction) and Part 2 (Importance). For example, A1. Health® refers to question #1 in Part 1 *and* question #1 in Part 2.

Total Quality of Life Score

All of the items are used to calculate the total score, which reflects overall quality of life.

Health and Functioning Subscale

1. Health
2. Health care
3. Energy (fatigue)
4. Ability to take care of yourself without help
5. Ability to control blood sugar
6. Changes made in life because of diabetes
7. Control over life
8. Chances for living as long as you would like
12. Sex life
17. Ability to take care of family responsibilities
18. Usefulness to others
19. Worries
26. Things for fun
27. Chances for a happy future

Social and Economic Subscale

14. Friends
16. Emotional support from people other than your family
20. Neighborhood
21. Home
- 22/23. Job/not having a job
24. Education
25. Financial needs

Psychological/Spiritual Subscale

28. Peace of mind
29. Faith in God
30. Achievement of personal goals
31. Happiness in general
32. Life satisfaction in general
33. Personal appearance
34. Self

Family Subscale

9. Family health
10. Children
11. Family happiness
13. Spouse, lover, or partner
15. Emotional support from family



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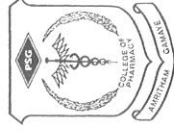
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